

Roche

Pharmaceuticals

July 27, 1999

Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

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Ladies and Gentlemen:

RE: Docket No. 98N-1215

Foreign Establishment Registration and Listing

Pursuant to the above-named proposed rule that was published in a *Federal Register* notice dated May 14, 1999 (Vol. 64, No. 93), the Agency is urged to revise the proposal to reflect that when a foreign establishment provides products for multiple US companies, there should be one US Agent listed per imported product, not per foreign establishment.

This request is based on the following:

This proposed rule would allow for only one US agent for each foreign establishment. Such a practice, however, would create opportunities for confusion as well as competitive harm, since a single foreign establishment could be supplying multiple US companies with products (especially APIs); therefore, a single US agent may not be practical or possible. For example, Foreign Establishment in Germany manufactures products for two pharmaceutical companies in the US -- Company A and Company B. If Foreign Establishment selects one of these two pharmaceutical companies as its US agent, significant conflicts of interest could arise where one company would be placed in the untenable position of acting as the agent for another pharmaceutical company. Clearly, in such a case it would be difficult, if not impossible, for the agent of record to have the best interests of a competing pharmaceutical company in mind.

Moreover, to resolve any problems encountered at the US port of entry, the burden is on the importer of record as shown on the US Customs entry form. Since import problems can originate from either FDA or US Customs, it is unclear how this difference in regulatory requirements would be reconciled. Under the current proposed rule, if Company A is selected as the US Agent for Foreign Establishment, what role, if any, could Company A play in resolving any import issues when Company B is the importer of record?

In light of the foregoing, the Agency is urged to consider requiring one US Agent listed per imported product, not per foreign establishment.

Respectfully submitted,

Hoffmann-La Roche Inc.

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HLR No. 1999-1814

98N-1215

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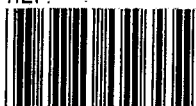
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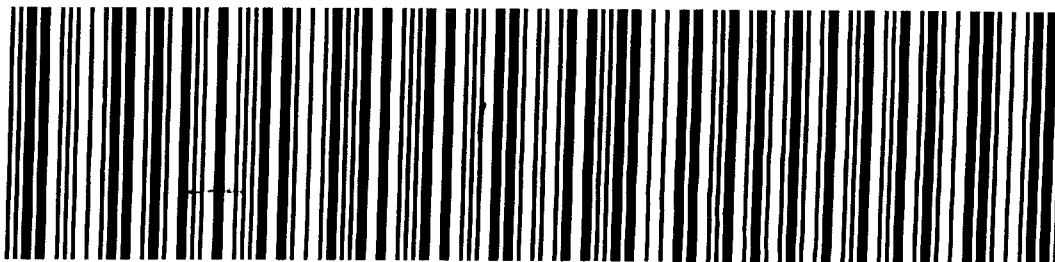
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